

### **Remarks**

This is in response to the final Office Action mailed April 6, 2007. Claims 1-8 and 21-24 remain pending. Reconsideration and allowance are requested for the following reasons.

#### **I. Claim Rejections - 35 U.S.C. § 102**

Claims 1 and 4-7 are rejected under 35 U.S.C. § 102(e) as being anticipated by Hunn et al., U.S. Patent Application Publication No. 2004/0158207 A1. This rejection is respectfully traversed, and reconsideration is requested for at least the following reasons.

Claim 1 recites, in part, allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by manually moving the needle of the insertion device from a retracted position to an extended position.

Hunn fails to disclose or suggest allowing a patient to manually move the needle of the insertion device from a retracted position to an extended position. The Action notes that the user presses a button 24 to trigger insertion of the cannula for the Hunn device. The cannula is thereupon automatically inserted by an inserting spring 21. See Hunn, ¶ 0073; Fig. 9. Therefore, although the button 24 is pressed by the user, the user is not allowed to manually move the needle of the insertion device from a retracted position to an extended position, as required by claim 1. Instead, the inserting spring 21, rather than the patient, moves the needle.

Hunn therefore fails to disclose or suggest allowing a patient to manually insert the cannula by moving the needle relative to the sleeve. In fact, Hunn teaches away from such a configuration, in that Hunn is critical of the devices disclosed in EP 0 290 176 (“EP ‘176”). Hunn, ¶ 0004. EP ‘176 discloses devices wherein the needle is manually inserted by the user, and then a spring is used to retract the needle. Consequently, Hunn teaches away from the device including manual insertion followed by retraction using a spring disclosed in EP ‘176.

Dependent claims 4-7 further define over Hunn. For example, claim 5 recites coupling the set to the site of the infusion device, including positioning the set in an unlocked position over the site, positioning the set onto the site; and moving the set from the unlocked position to a locked position to couple the set to the site and to introduce a needle of the set into a reservoir defined by the site. Further claim 6, which depends from claim 5, recites that the step of moving further comprises sliding a first member of the set relative to a second member of the set to move

the set from the unlocked position to the locked position. Hunn fails to disclose or suggest such methods recited in dependent claims 4-7.

Reconsideration and allowance of claim 1, as well as claims 4-7 that depend therefrom, are therefore requested.

## II. Claim Rejections - 35 U.S.C. § 103

### A. Claims 2 and 3

Claims 2 and 3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Mogensen et al., U.S. Patent Application Publication No. 2003/0109829. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claims 2 and 3 depend from claim 1. Mogensen does not remedy the shortcomings of Hunn noted above. For example, Mogensen fails to disclose or suggest allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by manually moving the needle of the insertion device from a retracted position to an extended position, as recited by claim 1. Reconsideration and allowance of claims 2 and 3 are therefore requested.

### B. Claim 8

Claim 8 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Hunn in view of Larsen et al., U.S. Patent No. 6,736,797. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 8 depends from claim 1. Larsen does not remedy the shortcomings of Hunn noted above. For example, Larsen fails to disclose or suggest allowing a patient to manually introduce the cannula of the infusion device into a subcutaneous layer of skin of the patient by manually moving the needle of the insertion device from a retracted position to an extended position, as recited by claim 1. Reconsideration and allowance of claim 8 are therefore requested.

### C. Claims 21-24

Claims 21-24 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Mogensen in view of Hunn. This rejection is respectfully traversed, and reconsideration is requested for the following reasons.

Claim 21 is directed to a method for introducing an infusion device. Claim 21 recites, in part, allowing a patient to manually move a needle of the insertion device from the delivery state to a trigger state to thereby introduce a cannula of a site into the skin.

Claim 21 is therefore allowable over Mogensen and Hunn for at least the same reasons as those provided above. Reconsideration and allowance of claim 21, as well as claims 22-24 that depend therefrom, are requested.

III. Conclusion

Favorable consideration in the form of a Notice of Allowance is requested. Please contact the undersigned attorney with any questions.

Respectfully submitted,  
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